



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Pelle et al.

Serial No.: 08/865,821

Group Art Unit: 1615

Filed: May 30, 1997

Examiner: Faulkner, Diedra

For: Lipid Mix for Lip Product

DECLARATION UNDER 37 C.F.R. §1.132

I, Philip Wesley Wertz, declare and say that:

1. I am a citizen of the United States and I reside at 1412 Laurel Street, Iowa City, IA 52240.
2. I am a professor at the University of Iowa, College of Dentistry located in Iowa City, IA, and I have an A.B. degree in Biochemistry from Rutgers University, New Brunswick, NJ and a Ph.D. degree in Biochemistry from the University of Wisconsin, Madison, WI. A copy of my curriculum vitae is attached hereto.
3. For over 20 years, I have taught, published and conducted research in the field of skin lipids. I have published numerous book chapters and articles related to skin lipids, including, in particular, the subject of the structure and function of lipids in the skin. I am very familiar with the scientific principles and issues related to the different structures and physiological roles of lipids in the skin and related to skin lipid research.
4. I have read U.S. Patent No. Zysman, U.S. Pat. No. 5,618,523 (hereinafter referred to as "the '523 reference") entitled "Ceramide, Process for Their Preparation and Their Applications in the Cosmetic and Dermopharmaceutical Fields" which relates to ceramides having a particular structure and compounds containing the ceramide. One of the compositions can be an aqueous dispersion of lipid spherules composed of organized molecular layers made of the ceramide and another lipid compound. The other lipid compound can be cholesterol, or cholesteryl sulphate or phosphate. I understand that the

Examiner in the present application has asserted that "cholesteryl esters are encompassed by the generic term, cholesterol" in this reference.

5. In my opinion, the Examiner's statement is incorrect. One of ordinary skill in the art recognizes that cholesteryl esters, cholesterol, and cholesteryl sulphate and phosphate are distinct compounds and treats each of these compounds as non-equivalent compounds due to their distinct distribution in the stratum corneum as well as their different functions in the stratum corneum. The '523 reference does not make a generic disclosure of cholesterol derivatives and the '523 reference does not disclose cholesteryl esters. More specifically, as applied directly to the Examiner's statement, it is my opinion that the mere recitation of the term "cholesterol" or "cholesteryl sulphate and phosphate" does not encompass cholesteryl esters.

6. Cholesterol is a major constituent of the stratum corneum, and it is believed to play a major role in the stratum corneum by contributing to the epidermal permeability barrier function and mediating desquamation of the skin. Moreover, cholesterol is a major component of the intercellular membrane system in the cornified layer of the epidermis. This intercellular membrane system provides the permeability barrier of the skin. In contrast, the cholesterol esters found in the cornified layer are not membrane forming lipids, and at a physiologic temperature they are liquid. The cholesterol esters in the cornified layer are thought to separate into isolated liquid phase pockets, and therefore, it is thought that cholesterol esters do not function as components of the intercellular membrane system.

7. Those skilled in the art also do not consider cholesterol and cholesteryl esters to be interchangeable. More specifically, because of the different functions of the compounds in the skin, one skilled in the art, on reading about a particular use for one of these compounds, would not assume that one of the other compounds would also function for the same purpose. This is evidenced by the separate treatment, both structurally and functionally, of cholesterol and cholesteryl esters in the scientific literature, especially literature pertaining to dermatology.

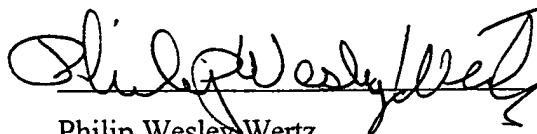
8. With respect to biochemistry and biology, one of ordinary skill in the physiological and/or dermatological arts recognizes that cholesterol, and cholesteryl sulphate and

phosphate, as disclosed in the '523 reference, are each individual compounds having individual qualities and functions in a physiological and/or dermatological system. Therefore, one of ordinary skill in the art would not interpret or imply that cholesterol, as it is disclosed in the '523 reference, includes cholesteryl ester nor would one of ordinary skill in the art be led to substitute cholesterol with cholesteryl esters.

9. In my opinion, based on the compositions taught in the '523 reference, it would not have been obvious to one of ordinary skill in the art to replace the cholesterol in the compositions of the '523 reference with the cholesteryl ester in the lipid mixture of the present invention.

10. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Date: 14 May 1999



Philip Wesley Wertz

FACULTY PROFESSIONAL BIOGRAPHY
College of Dentistry
University of Iowa

Date of preparation 12/12/98

I. Personal Data

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|------------------------------------|---|
| 1. Name <u>Philip Wesley Wertz</u> | 2. Social Security # <u>173-42-0860</u> |
| 3. Birth Date <u>10/25/49</u> | 4. Department <u>Oral Pathology, Radiology & Medicine</u> |
| 5. Present Rank <u>Professor</u> | 6. Date appointed to present rank <u>7/93</u>
Mo./Yr. |

II. Higher Education, formal programs (most recent first)

<u>Date Awarded</u> <u>(Mo./Yr.)</u>	<u>Degree</u>	<u>Major</u>	<u>Institution</u>	<u>Dates Attended</u>
1976	Ph.D.	Biochemistry	University of Wisconsin	1971-1976
1971	A.B.	Biochemistry	Rutgers University	1967-1971

III. Professional Employment: Appointments (most recent first)

<u>Mo./Yr.</u>	<u>Rank/Title</u>	<u>Institution</u>
1993- present	Professor	University of Iowa College of Dentistry Dows Institute for Dental Research
1990- 1993	Associate Professor	University of Iowa College of Dentistry and Dows Institute for Dental Research
1984- 1990	Assoc. Research Sci.	University of Iowa College of Medicine Department of Dermatology University of Iowa Iowa City, Iowa
1981- 1984	Assist. Research Sci.	University of Iowa College of Medicine Department of Dermatology University of Iowa Iowa City, Iowa
1979- 1981	Assoc. of the Laboratory	McArdle Laboratory for Cancer Research University of Wisconsin
1976- 1979	Postdoctoral Fellow	McArdle Laboratory for Cancer Research University of Wisconsin

IV. Certification and Licensure (Eligibility, stage of completion)

<u>Board</u>	<u>Date</u>
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V. Honors and Awards (most recent first)

Certificate of appreciation for lecture delivered at Catholic University Graduate School, Seoul, Korea (1996)

Certificate of appreciation for presentation at the annual meeting of the Cosmetic Chemists Society (1994)

Certificate of appreciation from NIH for participation in minority apprenticeship program (1992)

A.B. with highest honors (1971)

Phi Beta Kappa (1970)

VI. Professional Appointments (consultantships, editorships, review panels, etc.; most recent first)

<u>Year</u>	<u>Title</u>
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Reviewer for:
 Biochimica et Biophysica Acta
 Canadian Journal of Microbiology
 Chemistry and Physics of Lipids
 Journal of Investigative Dermatology
 Journal of Lipid Research
 Journal of Nutritional Biochemistry
 Lipids

and others

1992- Director of the Research Seminar Series

1992 External Reviewer for:
 Advisory Board for Research
 College of Dentistry
 The University of Illinois at Chicago

1991 Consultant for:
 Functions of Lipids in the Skin.
 Program Director: Donald T. Downing
 Department of Dermatology
 University of Iowa College of Medicine
 Program Project Grant Application -- not funded

- 1991- Ceramide Metabolism & Transport in Keratinocyte Cultures
Principal Investigator: Kathi Madison
Department of Dermatology
University of Iowa College of Medicine
RO-1 application -- active
- 1991- Effect of Nicotine on Inflammatory Mediators
Principal Investigator: Georgia Johnson
Department of Periodontics & Dows Institute
University of Iowa College of Dentistry
R-29 application -- active
- 1991- Effect of Nicotine on Inflammatory Mediators
Principal Investigator: Georgia Johnson
Department of Periodontics & Dows Institute
University of Iowa College of Dentistry
Funded by Smokeless Tobacco Council -- completed
- 1987 External Grant Reviewer for NIH
General Medicine A Study Section

VII. Committees (include chair and officer positions; most recent first)

<u>Year</u>	<u>Committee</u>	<u>Organization</u>
<u>National:</u>		
1995	Session Chairman, Presenter and Workshop Co-chairman at the Gordon Conference on the Barrier Function of the Skin	
1987	Session Co-chairman; Gordon Conference; Epithelial Differentiation and Keratinization: The Cell Periphery.	
<u>University:</u>		
1996-1998	Ethics and Scientific Misconduct Committee	
1992-1993	Biological Sciences Committee (Advisory Committee to the Vice President for Research) Pew Proposal Review Subcommittee (1992-1993)	
1997-1998	Biological Sciences Committee (Convener)	

1991-1997 Committee B (Human Subjects)
 1997- Committee A
 1997-1998 Library Committee

Collegiate:

1998- Senior Faculty Peer Review Committee
 1998 Periodontics Department Self Study Review Committee
 1996 Basic Science Subcommittee of the Curriculum Committee
 1991-1994 Research Committee
 1991- Student Dental Research Committee
 Special Advisory Subcommittee on Design and
 Conduct of Retrospective and Prospective
 Clinical Studies (1992-)

VIII. Professional Memberships (include offices held; most recent first)

<u>Year</u>	<u>Organization</u>
1992- 1993	Secretary/Treasurer of Iowa Chapter of AADR
1992-	ASBMB Congressional Correspondent
1991-	American Association for Dental Research
1989-	American Society for Biochemistry and Molecular Biology
1981-	American Oil Chemists Society
1981-	Society for Investigative Dermatology
1997-	American Association of Pharmaceutical Scientists
1998-	Controlled Release Society

IX. Areas of Research

Lipids of skin and oral epithelium -- structures, functions and metabolism
 Epithelial permeability and drug delivery
 Biochemistry of carcinogenesis
 Essential fatty acids

X. Current Projects

Compositions and structures of lipids from oral mucosa and skin
 Isolation and characterization of membrane coating granules
 Lipid alteration in hyperplasia
 Biochemical basis for oral mucosal drug delivery
 Preparation of liposomes for drug delivery
 Comparative enzymology of skin and oral epithelium.
 Quantitative morphology of oral epithelia
 Role of alcohol dehydrogenase in oral carcinogenesis

XI. Financial Resources (Grants and Contracts; include funded, pending, and approved but not funded applications; list most recent first in each category)

<u>Title</u>	<u>Role on Project</u> (eg: PI, Co-PI, consultant)	<u>Dates</u>	<u>Amount</u>
Federal:			
A Tissue Engineered Skin Model (RO1) Source: NIH Status: Pending Principal Investigator: Bozena Michniak Salary Support for PWW: 11% Comment: This is an RO1 Submitted from the University of South Carolina.	Contractor/Investigator	02/01/00- 01/31/03	
Local Effects of Alcohol, Aldehyde And Tobacco Carcinogens in the Pathogenesis of Oral Cancer Source: NIH/NIDR Status: Pending Principal Investigator: Christopher Squier Salary Support for PWW: 10% Comment: This is a component of a PPG.	Investigator	08/01/99- 03/31/04	
Production of Carcinogens by Oral Candida Strains Source: NIH/NIDR Status: Pending Principal Investigator: David Soll Salary Support for PWW: 5% Comment: This is a component of a PPG.	Investigator	08/01/99- 03/31/04	
Stratum Corneum Lipid Disks: A Novel Skin Model	Contractor/Collaborator	1-/01/99- 09/30/02	

Source: NIH
 Status: Pending
 Principal Investigator: Bozena B. Michniak
 Salary Support for PWW: 25%
 Comment: This is an ROI submitted from the University of South Carolina. The major focus is a series of studies on mechanisms of penetration enhancer action using lipid disks prepared at UI. Some EPR spectra and TEM work will also be done at Iowa.

<p>Tissue Engineering, Biomimetics And Medical Implant Science Source: NIH Status: Active Principal Investigator: Jackie Bickenbach Salary Support for PWW: 5% Comment: Lipid composition will be one of several markers used to judge epithelial differentiation in several bioengineered systems.</p>	<p>Investigator</p>	<p>08/01/98- 07/01/03</p>
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<p>Biological Basis For Oral Mucosal Drug Delivery. Source: NIH/NIDR Status: Active Principal Investigator: Christopher A. Squier Salary Support for PWW: 20% Comment: The proposed experiments would identify the physiochemical parameters required for effective drug delivery through the oral mucosa and would identify permeability enhancers for use in oral mucosal drug delivery systems.</p>	<p>Investigator</p>	<p>07/01/95- 06/31/98</p>	<p>\$474,624</p>
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<p>Effects Of Alcohol On Oral Mucosal Permeability. Source: NIH/NIDR Status: Approved but not funded</p>	<p>Principal Investigator</p>	<p>07/01/95- 06/31/97</p>	<p>\$70,835</p>
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Principal Investigator: Philip W. Wertz

Salary Support for PWW: 15%

Comment: The effects of alcohol on oral mucosal permeability to the tobacco carcinogen NNN would be examined. These studies could provide a mechanistic explanation for the association of alcohol and tobacco use with oral cancer.

<p>Transmucosal Peptide Delivery. Source: NIH/NIDR Status: Approved but not funded Principal Investigator: William Abraham Salary Support for PWW: 5% Comment: This is a Small Business Technology Transfer application. If funded we would collaborate with Cygnus Therapeutics Inc of Redwood CA on the development of trans oral mucosal peptide delivery systems.</p>	Investigator	07/01/95- 06/31/97	\$100,000
<p>Lipids And The Permeability Barrier of Oral Epithelium. Source: NIH-NIDR Status: Active Salary Support for PWW: 30% Comment: This grant would support studies on the formation, structure, permeability barriers. It would also include studies on the perturbation of barrier function by essential fatty acid deficiency.</p>	Principal Investigator	09/01/93- 08/31/97	\$403,504
<p>Epithelial Permeability; The Effects Of Age and Alcohol. Source: NIH-NIDR Status: Completed Principal Investigator: Christopher A. Squier Salary Support for PWW: 20% Comment: This grant supports work on the structure, lipid composition and permeability of human epithelia and the effects of aging on these parameters. Also, the effects of alcohol consumption on oral epithelial properties and carcinogenesis will be studied.</p>	Investigator	07/01/92- 06/30/95	\$328,611

<p>Structure And Function of Polar Lipids In Human Skin. Source: NIH-NIADDK Principal Investigator: Donald T. Downing Salary support for PWW: 60% Comment: PWW was involved in all phases of planning and execution of this project. This included extraction, isolation and analysis of epidermal lipids, synthesis of novel lipids, planning of metabolic experiments and formulation and testing of topical treatments.</p>	Investigator	12/01/83- 07/01/90	\$725,000
<p>Evaluation Of Pathogenic Factors In Acne Vulgaris. Source: NIH-NIADDK Principal Investigator: John S. Strauss Salary support for PWW: 40% Comment: As an Inversigator on this project, PWW was specifically responsible for isolation and analysis of polar lipids from normal skin and from patients with acne and scaling dermatoses.</p>	Investigator	04/15/81- 07/01/90	\$1,341,000
<p>College of Dentistry: none</p>			
<p>Other: Mucoadhesive Liposomes Source: Cellegy Pharmaceuticals Status: Active Comment: This project is linked To a US Patent application on Mucoadhesive liposomes. (\$30,000).</p>	Principal Investigator	08/30/98- 04/30/99	
<p>Lipid Dermatophysiology. Source: ConvaTec -- Bristol-Myers Squibb Status: Completed (\$56,900 in account) Comment: This project focuses on the effects of sebaceous lipids, synthetic lipids and liposomes on</p>	Principal Investigator	10/30/91- 12/31/94	\$105,00

properties of the skin surface including permeability and adhesive performance. It is renewable on an annual basis at \$35,000 per year.

Ceramides & Ceramidases of Skin

Principal Investigator

01/01/95-
12/31/95

Source: Gist-brocades

Status: Completed (\$1,788 remaining)

Comment: This project involved several experiments in which the penetration of ceramides into stratum corneum was monitored, and the activity of ceramidase in epidermal homogenates was assayed. (Total costs - \$5,000)

Lipid Analytical Service

Principal Investigator

11/15/90 -

Source: Various Agencies

Status: Active on an intermittent basis (\$40,000 currently in account)

This is a service with prospects of long term continuity and accumulation of small amounts of money in exchange for occasional advise or analytical services.

Roles of Lipids In Desquamation.

Co-Principal Investigator

07/01/86- \$300,00
07/01/90

Source: The Procter & Gamble Company

Co-Principal Investigators: Donald T. Downing & Philip W. Wertz

Comment: This contract was renewed on an annual basis at \$75,000 per year.

Roles Of Lipids In Cosmetic Properties of The Skin.

Investigator

4/15/81- \$200,000
6/30/86

Source: Richardson Vicks Inc.

Principal Investigator: John S. Strauss

Comment: PWW was an investigator on this contract, which provided partial salary support during 1981-1983 and supplemented funds available through federal grants. The

contract was renewed on an annual basis. It started at \$25,000 per year, and ended at \$75,000 per year.

XII. Bibliography (attach sections in the following order, with authors in sequence; most recent first; list work that is published or "in press". Submitted work may also be listed; include journal title and date of submission; manuscripts in progress should not be included)

1. Books and/or Chapters

Wertz PW, Michniak BB: Epidermal lipid metabolism and barrier function of stratum corneum. In: BIOMEDICAL MODULATIONS OF SKIN REACTIONS IN DERMAL AND TRANSDERMAL DRUG DELIVERY, JJ Wille, A. Kydonieus (Eds), CRC Press, Boca Raton, 1999, in press

Michniak BB, Wertz PW: Ceramides and lipids. In: HANDBOOK OF COSMETIC SCIENCE AND TECHNOLOGY, HI Maibach, A Barel, M Paye (Eds.), Marcel Dekker, New York, 1999, in press

Wertz PW: Integral lipids of hair and stratum corneum. In Hair: Biology And Structure, H. Zahn and P. Jolles, Eds., Birkhauser Verlag, Basel,, 1996, pp 227-238.

Wertz PW: Skin lipids in health and disease. In Phospholipids: Characterization, Metabolism and Novel Biological Applications, G. Cevc, F. Paltauf, Eds., AOCS Press, Champaign, IL, pp 141-160, 1996.

Wertz PW: Percutaneous absorption: Role of lipids, In Dermatotoxicology - 5th Edition, H.I. Maibach and F.N. Marzulli, Eds., Taylor and Francis, Washington DC, pp 29-32, 1996

Wertz PW, Hoogstraate AJ, Squier CA: Biochemical basis of the permeability barrier in skin and oral mucosa. In Oral Mucosa Drug Delivery, M.J. Rathbone and J. Hadgraft, Eds., Marcel Dekker, Inc., New York, pp 27-49, 1996

Squier CA, Wertz PW: Structure and function of the oral mucosa and implications for drug delivery. In Oral Mucosal Drug Delivery, MJ Rathbone, Ed., AAI Inc, Wilmington, pp 1-26, 1996

Wertz PW, Squier CA: Biochemical Basis of the Permeability Barrier in Skin and Oral Mucosa. In Oral Mucosal Drug Delivery, MJ Rathbone, Ed., AAI Inc, Wilmington, pp 1-26, 1996

Squier CA, Wertz PW, Williams DM, Cruchley AT: Permeability of oral mucosa and skin with age. In The Effect Of Aging In Oral Mucosa And Skin, C.A. Squier and M.W. Hill, Eds., CRC Press, Boca Raton, pp 91-98, 1994.

- Wertz PW, Karthigasan J, Hill MW: Effects of Aging on Epithelial Metabolism. In *The Effect of Aging In Oral Mucosa And Skin*, C.A. Squier and M.W. Hill, Eds., CRC Press, Boca Raton, pp 107-112, 1994.
- Downing DT, Stewart ME, Wertz PW, Strauss JS: Lipids of the epidermis and the sebaceous glands. In *Dermatology In General Medicine*, 4th edition, TB Fitzpatrick, AZ Eisen, K Wolff, KF Austen (eds.) McGraw-Hill, Inc., New York, 210-211, 1993.
- Wertz PW, Downing DT: Biology and biochemistry of the epidermis. In *Biochemistry And Physiology Of The Skin*, 2nd edition, LA Goldsmith (Ed.) Oxford University Press, New York, 1992.
- Wertz PW: Liposome dermatics -- chemical aspects of the skin lipid approach. In: *Liposome Dermatics*, O. Braun-Falco, HC Korting, HI Maibach (Eds.), Springer-Verlag, Berline, 1992, pp 38-43.
- Wertz PW, Swartzendruber DC, Downing DT: The role of the corneocyte lipid envelope in the structure and function of the epidermal barrier. In *Proceedings Of The Conference On Prediction Of Percutaneous Penetration*, RC Scott, J Hadgraft, RH Guy, J McDougal (Eds.), IBC Technical Services Ltd., London, 1990, pp. 405-411.
- Downing DT, Stewart ME, Wertz PW, Strauss JS: The effect of sebum on epidermal lipid composition. In *Acne And Related Disorders*, R Marks, G Plewig (Eds.) Martin Dunitz, London, 1989.
- Wertz PW, Downing DT: Stratum corneum: biological and biochemical considerations. In *Transdermal Delivery Systems*, J Hadgraft, RH Guy (Eds.), Marcel Dekker, NY, 1988.
- Wertz PW: Lipids of keratinized tissues. In *Biology Of The Integument*, Vol. 2. J Bereiter-Hahn, GA Matoltsy, KS Richards (Eds.), Springer-Verlag, Berlin, 1986.
- Wertz PW: Effects of phorbol esters on phospholipid metabolism in vitro. In *Arachidonic Acid Metabolism And Tumor Promotion*, Vol. 3. TJ Slaga, SM Fisher (Eds.), Martinus Nijhoff Publishing, Boston, 1985.
2. Journal Articles (include initial and final page numbers)
- Di Nardo A, Wertz PW, Giannetti A, Seidenari S: Ceramide and cholesterol composition of the skin of patients with atopic dermatitis. *Acta Derm Venereol (Stockh)* 78:27-30, 1998
- Madison KC, Sando GN, Howard EJ, True CA, Gilbert D, Swartzendruber DC, Wertz PW: Lamellar granule biogenesis: a role for ceramide glucosyltransferase, lysosomal enzyme transport, and the golgi. *J Invest Dermatol Symp Proc* 3:80-86, 1998
- Kuempel D, Swartzendruber DC, Squier CA, Wertz PW: In vitro reconstitution of stratum corneum lipid lamellae. *Biochim Biophys Acta* 1372:135-140, 1998

- Wertz PW, van den Bergh BAI: The Physical, chemical and functional properties of lipids in the skin and other biological barriers. *Chem Phys Lipids* 91:85-96, 1998
- van den Bergh BAI, Bouwstra JA, Junginger HE, Wertz PW: Interaction of flexible liquid-state niosomes with hairless mouse skin, assessed by electron microscopy, in vivo, and by diffusion studies in vitro. *Proceed Int Symp Control Rel Bioact Mater* 25:18-19, 1998
- Law S, Fotos PG, Wertz PW: Skin surface lipids inhibit adherence of *Candida albicans* to stratum corneum. *Dermatology* 195:220-223, 1997
- Whittle S, Swartzendruber DC, Kremer M, Squier CA, Wertz PW: Lipids of hamster cheek pouch epithelium. *Lipids* 32:961-964, 1997
- Hoogstraate AJ, Wertz PW, Squier CA, Bos-van Geest A, Abraham W, Garrison MD, Verhoef JC, Junginger HE, Bodde HE: Effects of the penetration enhancer glycodeoxycholate on the lipid integrity in porcine buccal epithelium in vitro. *Euro J Pharm Sci* 5:189-198, 1997
- Atar PS, Wertz PW, McArthur M, Imakado S, Bickenbach JR, Roop DR: Inhibition of retinoid signaling in transgenic mice alters lipid processing and disrupts epidermal barrier function. *Molecular Endocrin* 11:792-800, 1997
- Squier CA, Kremer M, Wertz PW: Continuous flow mucosal cells for measuring the in vitro permeability of small tissue samples. *J Pharm Sci*, 86:82-84, 1997
- Di Nardo A, Sugino K, Ademola J, Wertz PW, Maibach HI: Role of ceramides in proclivity to toluene and xylene-induced skin irritation. *Dermatosen* 44:119-125, 1996
- Di Nardo A, Sugino K, Ademola J, Wertz PW, Maibach HI: Sodium lauryl sulfate (SLS) induced irritant contact dermatitis: a correlation study between ceramides and in vivo parameters of irritation. *Contact Dermatitis*. 35:86-91, 1996
- Law S, Wertz PW, Swartzendruber DC, Squier CA: Regional variation in content, composition and organization of porcine epithelial barrier lipids revealed by thin-layer chromatography and transmission electron microscopy. *Archs oral Biol* 40:1085-1091, 1995
- Swartzendruber DC, Manganaro A, Madison KC, Kremer M, Wertz PW, Squier CA: Organization of the intercellular spaces of porcine epidermal and palatal stratum corneum: a Quantitative study employing ruthenium tetroxide. *Cell & Tissue Res* 279:271-276, 1995.
- Swartzendruber DC, Burnett IH, Wertz PW, Madison KC, Squier CA: Osmium tetroxide and ruthenium tetroxide are complementary reagents for the preparation of epidermal samples for transmission electron microscopy. *J Invest Dermatol*, 104:417-420, 1995.
- Vargas K, Wertz PW, Drake D, Morrow B, Squier CA, Soll DR: Differences in adhesion of the switch phenotypes of *Candida albicans* strain 3153A to buccal epithelium and stratum corneum. *Infection and Immunity*, 62:1328-1335, 1994.

- Johnson GK, Poore TK, Squier CA, Wertz PW, Reinhardt RA, Vincent SD: Prostaglandin E2 and interleukin-1 levels in smokeless tobacco-induced oral mucosal lesions. *J Periodont Res*, 29: 430-438, 1994.
- Abraham W, Wertz PW, Potts RO, Garrison MD: Investigation of phase transition in oral mucosa by fluorescent spectroscopy. *Proc Internat Symposium Control Release Bioact Mater*, 21:557-558, 1994.
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- Di Nardo A, Sugino K, Wertz PW, Ademola J, Maibach HI: Cutaneous reactions to the organic solvents toluene and xylene: determination of surface lipids and instrumental determination of inflammatory reaction. *Dermatologia Oggi* 2:17-21, 1993.
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- Wertz PW, Downing DT: Integral lipids of mammalian hair. *Comp Biochem Biophys* 92B:759-761, 1989.
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- Wertz PW, Downing DT: β -Glucosidase activity in porcine epidermis. *Biochim Biophys Acta* 1001:115-119, 1989.
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- Abraham W, Wertz PW, Landmann L, Downing DT: Preparation of liposomes and lamellar sheets from stratum corneum lipids. Annual meeting of the Society for Investigative Dermatology, 1986. Clin Res 34:733A, 1986.
- Burken RR, Wertz PW, Abraham W, Downing DT: The occurrence of "molecular rivets" in epidermis from different orders of vertebrates. Annual meeting of the Society for Investigative Dermatology, 1986. Clin Res 34:741A, 1986.
- Wertz PW, Downing DT: Linoleic acid in epidermal acylglucosylceramide from newborn, growing and mature mice. Annual meeting of the Society for Investigative Dermatology, 1985. Clin Res 34:787A, 1986.
- Madison KC, Wertz PW, Downing DT, Strauss JS: Lipid composition of cultured murine keratinocytes. Annual meeting of the Society for Investigative Dermatology, 1986. Clin Res 34:765A, 1986.
- Squier CA, Cox P, Lesch CA, Wertz PW: Identification of lipids in successive epithelial strata of skin and oral mucosa. International Association for Dental Research meeting, 1985.
- Stewart ME, Wertz PW, Grahek MO, Downing DT: Relationship between sebum secretion rates and the concentration of linoleate in sebum and epidermal lipids. Annual meeting of the Society for Investigative Dermatology, 1985. Clin Res 33:684A, 1985.
- Ranasinghe AW, Wertz PW, Mackenzie IC, Downing DT, Strauss JS: The role of lipids in corneocyte cohesion and desquamation in mouse ear skin. Annual meeting of the Society for Investigative Dermatology, 1985. Clin Res 33:677A, 1985.
- Abraham W, Wertz PW, Downing DT: Linoleate-rich polar lipids of epidermis: structure determination by proton magnetic resonance. Annual meeting of the Society for Investigative Dermatology, 1985. Clin Res 33:621A, 1985.
- Long SA, Wertz PW, Strauss JS, Downing DT: Human stratum corneum polar lipids before and after desquamation. Annual meeting of the Society for Investigative Dermatology, 1983. Clin Res 32:599A, 1984.
- Landmann L, Wertz PW, Downing DT: Acylglucosylceramide causes flattening and stacking of liposomes: an analogy for assembly of the epidermal permeability barrier. Annual meeting of the Society for Investigative Dermatology, 1984. Clin Res 32:596A, 1984.
- Wertz PW, Downing DT: The role of glycolipids in assembly of extracellular membranes in the skin. Annual meeting of the Iowa Academy of Science, 1984.

- Landmann L, Wertz PW, Downing DT: Acylglucosylceramide and the epidermal permeability barrier: a liposome reconstitution study. Annual meeting of the European Anatomical Society, 1984. *Acta Anatomica* 120:241-242, 1984.
- Cox PS, Wertz PW, Downing DT, Squier CA: Changes in lipid composition between consecutive sections through pig epidermis. Annual meeting of the British Society for Investigative Dermatology, 1984.
- Downing DT, Stewart ME, Wertz PW, Colton SW 6th: Analysis of waxes from vertebrate skin. Annual meeting of the American Oil Chemists Society, 1984. *J Amer Oil Chem Soc* 61:666, 1984.
- Clancey CJ, Van Orden DE, Zlatnik FJ, Wertz PW, Downing DT: Quantitation of amniotic fluid phospholipids: A novel determination of disaturated lecithins (SPC). Annual meeting of the Society for Gynecologic Investigation, 1983.
- Wertz PW, Downing DT: Epidermal sphingolipids: structures and possible functions in the epidermal water barrier. Annual meeting of the Society for Investigative Dermatology, 1983. *Clin Res* 31:608A, 1983.
- Wertz PW, Downing DT: Studies on the role of glycolipids in the assembly and maintenance of the extracellular membranes in the skin of terrestrial vertebrates. Twelfth International Congress of Biochemistry, 1982.
- Wertz PW, Downing DT: The structures and physiological role of lipids in the epidermal barrier to percutaneous water loss. Annual scientific meeting of the Society of Cosmetic Chemists, 1982.
- Wertz PW, Mueller GC: A role for protein alkylation in phorbol ester action. Annual meeting of the American Association for Cancer Research, 1981. *Proc Amer Assoc Cancer Res* 22:137, 1981.
- Wertz PW, Mueller GC: Activation of CTP:phosphorylcholine cytidyl transferase by 12-0-tetradecanoylphorbol-13-acetate (TPA) in bovine lymphocytes. Annual meeting of the American Association for Cancer Research, 1980. *Proc Amer Assoc Cancer Res* 21:511, 1980.
- Wertz PW, Mueller GC: 5,8,11,14-Eicosatetraenoic acid (ETYA) inhibits the biological action of 12-0-tetradecanoylphorbol-13-acetate (TPA) in bovine lymphocytes. Annual meeting of the American Association for Cancer Research, 1979. *Proc Amer Assoc Cancer Res* 20:949, 1979.
- Mueller GC, Kensler TW, Wertz PW, Kwong CH: Retinoic acid inhibition of phorbol ester mediated comitogenesis, phospholipid metabolism and capping in bovine lymphocytes. Cold Spring Harbor Symposium on Phorbol Esters, 1978.

Wertz PW, Mueller GC: 12-0-Tetradecanoylphorbol-13-acetate stimulates phosphatidyl choline metabolism in bovine lymphocytes. Annual meeting of the American Society of Biological Chemists, 1978. Fed Proc 37:1494, 1978.

Wertz PW: A computer assisted kinetic analysis of the tautomerization and complex mutarotation of D-galactose. Doctoral dissertation, University of Wisconsin, Madison (1976). Dissertation Abstracts International 37:4450-B, 1977.

Anderson L, Wertz PW: Correlation between the complex mutarotation of an aldose and the kinetics of its tautomerization. Centennial meeting of the American Chemical Society, 1976.

5. Invited External Presentations and Lectures

Presented an invited lecture titled "Regional variation in lipids and barrier function in keratinizing epithelia" at the conference on Perspectives on Percutaneous Penetration in Leiden, September, 1998.

Seminars at the University of Modena, University of Leiden, University of South Carolina, Medical University of South Carolina, University of California at San Francisco and University of Iowa College of Dentistry and College of Medicine, 1998.

Invited speaker at the Gordon Conference on the Barrier Function of Mammalian Skin, New Hampshire, 1997.

Invited speaker at the World Congress of Dermatology, Sydney, Australia, 1997.

Presented an invited lecture titled "Skin lipids in health and disease" at Catholic University, Seoul, Korea, August, 1996

Presented an invited lecture titled "Effects of lipids on the cosmetic properties of the skin" at Pacific Research and Development Center, Seoul, Korea, August, 1996

Presented an invited lecture titled "Lipids and the epidermal permeability barrier" at the annual meeting of the Korean Society for Investigation of the Barrier Function of the Stratum Corneum, Seoul, Korea, August, 1996

Presented an invited lecture titled "Chemistry and composition of lipids from the skin surface, stratum corneum and hair" at Amway Research Center, Grand Rapids, MI, October 1995

Presented an invited lecture titled "Lipids and the epidermal permeability barrier" at ALZA Corporation, Palo Alto, CA, September 1995

Invited speaker at the Gordon Conference on Barrier Function of Mammalian Skin. Also co-directed an afternoon workshop on the ROLES OF LIPIDS IN BARRIER FUNCTION.

Presented an invited lecture titled "Lipids and the epidermal permeability barrier" at the annual scientific meeting of the Society of Cosmetic Chemists, New York, 8-9 December, 1994.

Presented an invited lecture titled "Antimicrobial lipids from the skin surface" at ConvaTec, a subsidiary of Bristol-Myers Squibb, Princeton, NJ, December 1994.

Served as co-chairman at the Dental Student Research Conference, 1990, 1992 & 1994.

Presented an invited lecture titled "Epidermal lipids -- opportunities for transdermal drug delivery and improved skin adhesives" at ConvaTec, a subsidiary of Bristol-Myers Squibb, Princeton, NJ, October 1993.

Presented an invited lecture titled "Skin lipids in health and disease" at The 6th International Colloquium on Phospholipids, Hamburg, Germany, 24-27 October, 1993.

Presented an invited lecture titled "The epidermal permeability barrier -- biochemical and ultrastructural considerations" Second Annual New Technologies Workshop: Skin Toxicology And Pharmacology -- In Vitro And Clinical Techniques, Microbiological Associates, Inc., Bethesda, MD, 9-10 September 1993.

Presented an invited lecture titled "Roles of lipids in formation and function of the epidermal permeability barrier and the influence of skin surface lipids on adherence of *Candida albicans*" at the ConvaTec Skin Care Symposium, Princeton, NJ, 14 May 1993

Presented an invited lecture titled "Composition, structure and organization of lipids in stratum corneum" at The Winter Workshop (The Physical Organization of Stratum Corneum Lipid) held at the University of British Columbia, Vancouver, Canada, February 28 - March 2, 1993

Served as a judge of the Max Smith Award competition at the 1992 annual meeting of the Iowa Chapter of the American Association for Dental Research

Speaker at conference on the effects of aging on oral mucosa and skin held in Iowa City, May 1992.

Presented an invited lecture titled "Lipid nature of the epidermal permeability barrier" at ConvaTec, a subsidiary of Bristol-Myers Squibb, Princeton, NJ, 1991.

Speaker and session chairman at International Conference on Liposome Dermatics in Bad Griesbach, Germany, October 1991.

Presented invited lecture titled "Essential fatty acids and epidermal integrity" at the 36th Annual Symposium on the Biology of the Skin sponsored by the Cutaneous Biology Foundation, Inc., Salishan Lodge, Oregon, 1986.

Presentations on epidermal lipids at Vicks Research Center, Shelton, CT, in 1982, 1983 and 1984.

Presented and invited lecture title "Structure and function of the polar lipids of epidermis" at the Gordon Conference on Epithelial Differentiation and Keratinization, 1983.

Presented invited lecture titled "The structure and physiological role of lipids in the epidermal barrier to percutaneous water loss" at the annual meeting of the Society of Cosmetic Chemists, New York. 1982.

6. Other: Exhibits, films, tapes, special presentations

XIII. Student Mentoring:

1. Graduate Theses Directed:

<u>Degree</u>	<u>Year</u>	<u>Candidate</u>	<u>Title</u>
M.S. (Co-Directed with Pete Fotos)	1993	Sandra Law	Adherence of <u>Candida albicans</u> to porcine stratum corneum in vitro.
M.S.	1992	Albert Manganaro	Effects of permeabilizers on penetration of propranolol through buccal epithelium in vitro.
M.S.	1997	Patricio Jarpa	Variations of pH, nicotine levels and mutagenicity of smokeless tobacco products from U.S., India and Venezuela

I have served or am serving on the thesis committees of:

Deborah Vezeau
 David Rolf
 Thomas Poore
 Riaz Ali
 Bruce Ringdahl
 Hudda Hamaddi
 Mike Huberman
 Joseli Alves
 Deena Kuempel
 Earnest Lam
 Kaaren Vargas
 Heather Reid
 Xiobing Du

2. Other Graduate Committee Service:

<u>Degree</u>	<u>Year</u>	<u>Candidate</u>	<u>Title</u>
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3. Predoctoral Student Research Mentorship:

<u>Student</u>	<u>Year</u>	<u>Awards Received by Student</u>
Benedicte van den Bergh (Dutch Ph.D. student)	1998	
Jennifer Garza	1997-	Dows Award NIDR Award
Matt Howard	1998 -	NIDR Award
Manal Ahmad	1997 -	DRA
Rebecca Guo	1998 -	Dows Award
Shannon Li	1998 -	DRA
Kevin Ortale	1994-1997	Max Smith Award NIDR Awards
Janet Hoogstraate (Dutch PhD student)	1994	
Sara Whittle	1995-1998	NIDR Awards

Trace Lund (David Drake Co-Mentor)	1994-1997	DRA
Matt Grau (Kevin Donly Co-Mentor)	1996	Director's Award
Doug Squier (predental 1995, dental student 1996-)	1995-	Dows Award DRA
Delon Gilbert (Predental, dental student 1997-)	1996-1997	Howard Hughs Fellowship Dows Award AADS Gies Award
Keith Slaymaker (Predental)	1996-1998	
Matt Abraham (Predental)	1996	
P. Bayati	1993-1995	Director's Award Dows Award
Ajanet Mclain (SSTP)	1994	
G Gell	1993-1995	Dows Award
Candace Wright (SSTP)	1993	
Aima Ahonkai (SSTP)	1993	
Felicia Chang	1991-1994	Dows Awards
Niki Holbrook (SSTP)	1992	
Harry Fang (local high school student; Science Research 91:86)	1992	
Nate Stevens (Predental)	1991	
William B Shade II (SSTP, CA Squier Co-Mentor)	1991	

Karen N. Ekpenyong 1991
(SSTP, CA Squier Co-Mentor)

Sofia F. Betancourt 1991
(SSTP, David Drake Co-Mentor)

Jennifer Haake 1991
(local high school student; Science Research 91:86)

Jeffrey T Bortz 1990
(Medical Student)

Christopher L Hedberg 1989
(Medical Student)

Kathy M Perisho 1988
(Medical Student)

Mark A Wix 1987
(Medical Student)

Jeffrey C Melton 1987
(Medical Student)

Russel R Burken 1983-1984
(Medical Student)

Susan Rubes 1986
(Medical Student)

Paul M Stover 1986
(Medical Student)

Saundrett Gibbs 1985
(Medical Student)

Dan Johnson 1985
(Medical Student)

Marianne C Miethke 1985
(Medical Student)

Sherri Long 1985

Best Basic Science Presentation
Best Clinical Presentation
Best Presentation in Dermatology
All at the 1986 Medical Student
Research Symposium at Galveston

Richard T Schoephoerster 1985
(Undergraduate)

Mark L Frost 1984
(Medical Student)

Craig Birkby 1982
(Medical Student)

XIV. Continuing Education (sponsored by the University; presented during the past five years most recent first)

Presentations qualifying for continuing education credit at:
Dermatology meetings & symposia 20
Clinical research meeting 1
Seminars 2

XVI. Teaching Activities (Include the past five years; most recent first; provide narrative describing responsibility in each course)

1. Classroom, Seminar, or Teaching Laboratory

<u>Year</u>	<u>Course Title and No.</u>	<u>No. registered</u>	<u>length of course</u>
1996-	Systemic Disease Manifestations 86:155 facilitator for problem based learning	75	16 wks
1993-	Pathophysiology of Skin & Mucosa 112:251	9	16 wks
1992-95	Dental Biochemistry 99:161	70	16 wks
1991-	Dental Science Research Methodology 151:210 Course Director	31	8 wks
1991-	Research Seminar Series 151:200 Director	15	16 wks 100%
1991-	Pathophysiology of Salivary	12	16 wks 10%

Glands 112:254

1990-91	Dental Science Research Methodology 112:210	25	8 wks 10%
1982-90	Basic Science for Dermatology College of Medicine	12	16 wks 25%
1982-90	Research in Dermatology 62:4	6	16 wks 35%

2. Clinical Teaching (undergraduate, graduate and direct patient care)

<u>Year</u>	<u>Where Occurred</u>	<u>weeks/year</u>	<u>hrs/wk</u>
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Students supervised:

- 2 local high school students
 - 7 SSTP students
 - 6 University of Iowa undergraduates
 - 14 medical students
 - 14 dental students
 - 3 College of Dentistry MS students
 - 1 high school science teacher
 - 2 postdoctoral associates
 - 2 Dutch PhD students
- see pages 25-32 for details.